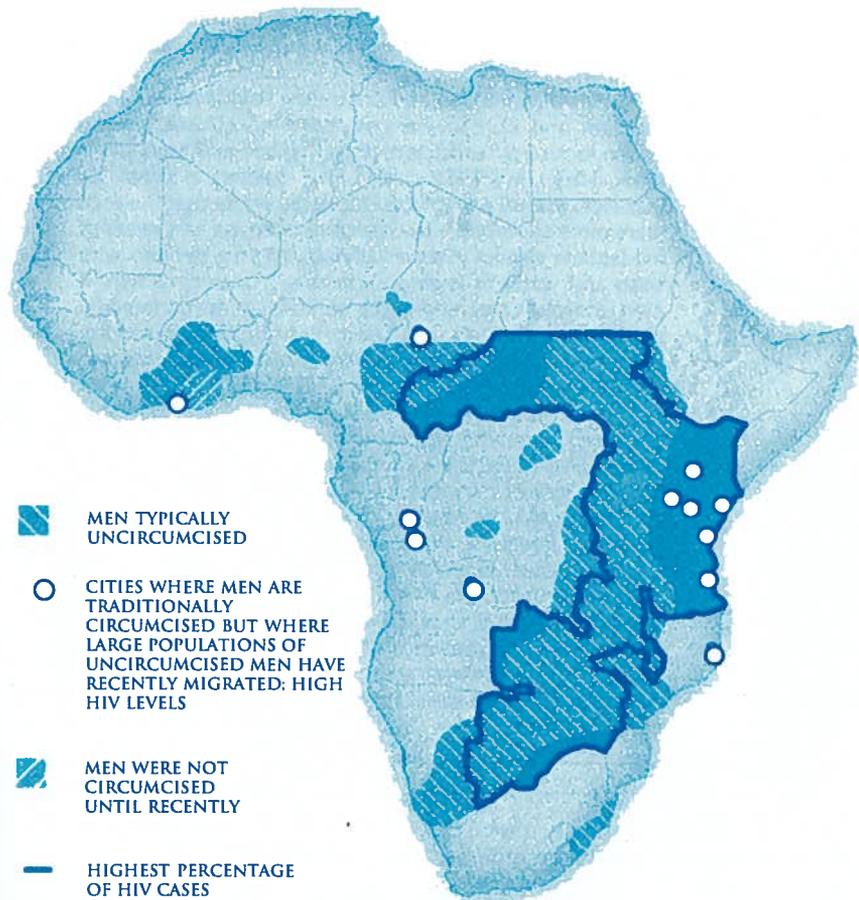


REGIONS IN AFRICA WHERE MOST MEN ARE UNCIRCUMCISED



Scientific American 1996

# Male Circumcision: *Current Epidemiological and Field Evidence*

Program and Policy Implications  
For HIV Prevention and Reproductive Health

September 18 and 19, 2002  
Conference Report



Sponsored by  
USAID Office of HIV/AIDS, AIDSMark (PSI, PATH, MSH), JHPIEGO

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AIDSMark is a ten-year, worldwide program, started in 1997, that uses social marketing to combat the spread of HIV/AIDS and other sexually transmitted infections.

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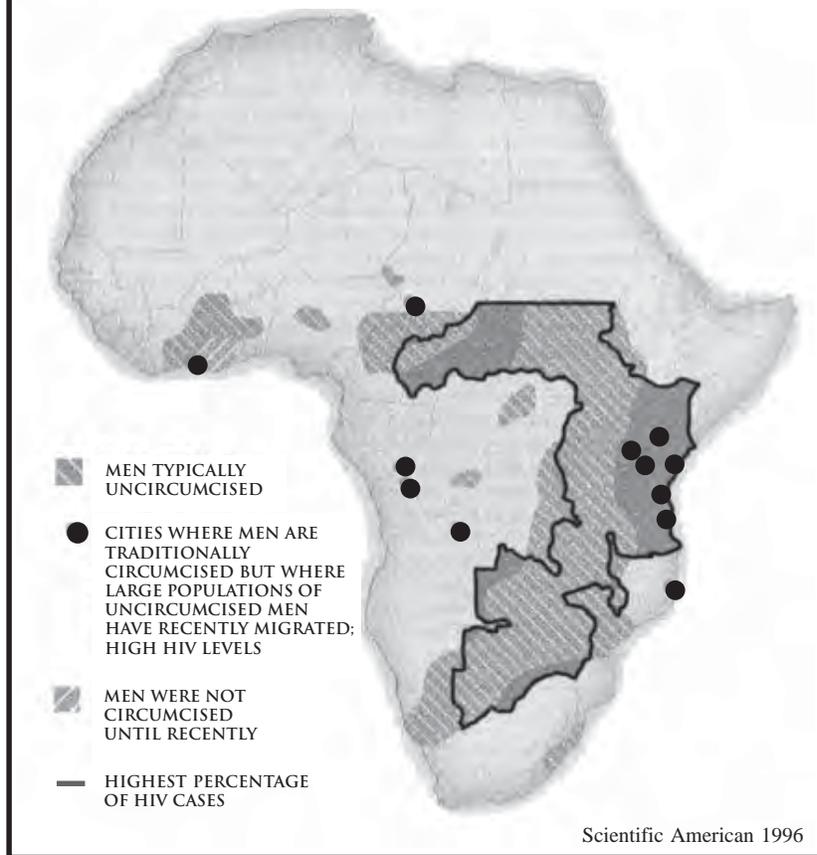
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# Acronyms

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<b>AIDS</b>	Acquired immunodeficiency syndrome
<b>AIDSMark</b>	AIDS Marketing Project
<b>BSS</b>	Behavior Surveillance Survey
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CI</b>	Confidence interval
<b>DHS</b>	Demographic and Health Survey
<b>FGC</b>	Female genital cutting
<b>HIV</b>	Human immunodeficiency virus
<b>HPV</b>	Human papilloma virus
<b>HSV</b>	Herpes simplex virus
<b>IEC</b>	Information, education, and communication
<b>JHPIEGO</b>	Johns Hopkins Program for International Education Corporation
<b>MC</b>	Male circumcision
<b>MOH</b>	Ministry of health
<b>MSH</b>	Management Sciences for Health
<b>MTCT</b>	Mother-to-child transmission
<b>NGO</b>	Nongovernmental organization
<b>NIH</b>	National Institutes of Health
<b>OR</b>	Operations research
<b>PATH</b>	Program for Appropriate Technology in Health
<b>PMTCT</b>	Prevention of mother-to-child transmission
<b>PSI</b>	Population Services International
<b>RCT</b>	Randomized controlled trial
<b>RH</b>	Reproductive health
<b>RR</b>	Risk ratio
<b>STD</b>	Sexually transmitted disease
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNICEF</b>	United Nations Children's Fund
<b>UNFPA</b>	United Nations Population Fund
<b>USAID</b>	United States Agency for International Development
<b>VSS</b>	Voluntary surgical sterilization
<b>WHO</b>	World Health Organization

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# *Acknowledgements*

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This conference was sponsored by the United States Agency for International Development (USAID) Office of HIV/AIDS through the AIDSMark project with participation of Population Services International (PSI), the Program for Appropriate Technology in Health (PATH), and Management Sciences for Health (MSH). JHPIEGO also participated in all aspects of the planning and implementation of the conference. A sincere thanks is expressed to all of the presenters, facilitators, and rapporteurs for this event, many of whom traveled great distances without remuneration to share their work. In addition, we wish to acknowledge the support of many staff from other USAID offices, including the Office of Population and Reproductive Health.



# Executive Summary

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## Day 1 Meeting

On September 18 and 19, 2002, the United States Agency for International Development (USAID) and its partner organizations AIDSMark and JHPIEGO held technical meetings to examine the relationship between male circumcision (MC) and HIV transmission and other health concerns, including penile and cervical cancer. This relationship has become increasingly important to epidemiologists as well as to AIDS and reproductive health (RH) program staff. Day 1 was attended by 145 experts, including many participants from the preceding day's technical meeting (also organized by USAID) on "ABC"<sup>1</sup> behavior change approaches to primary HIV/AIDS prevention (<http://www.synergyaids.com/show.asp?id=3750&type=18>). These guests included researchers and program staff from the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Canadian International Development Agency (CIDA), the Gates Foundation, most of USAID's collaborating partner agencies in HIV/AIDS and population programming, and several North American and European universities. The Day 1 presentations are posted at [http://www.rho.org/html/menrh\\_mtg\\_mc\\_09\\_02.html](http://www.rho.org/html/menrh_mtg_mc_09_02.html). The goals of the Day 1 meeting were to:

- Present previously existing and emerging epidemiological and biological data on MC and the status of recent MC introduction studies and clinical trials.
- Discuss policy and implementation issues toward achieving consensus on a) when it may be appropriate to begin developing programs for providing MC services; b) how best to then proceed; and c) with which populations (i.e., traditionally circumcising or non-circumcising populations, which age groups, etc.).
- Address other key concerns and challenges related to MC assessment and introduction.
- Identify further research and program priorities.

The following five key aspects of MC were presented:

**1. Current Epidemiological and Biological Evidence:** A systematic review and meta-analysis of 28 published studies by the London School of Hygiene and Tropical Medicine, published in the journal *AIDS* in 2000, found that circumcised men are less than half as likely to be infected by HIV as uncircumcised men. A subanalysis of 10 African studies found a 71 percent reduction among higher-risk men. A September 2002 update considered the results of these 28 studies plus an additional 10 studies and, after controlling for various potentially confounding religious, cultural, behavioral, and other factors, had similarly robust findings. Recent laboratory studies in Chicago found HIV uptake in the inner foreskin tissue to be up to nine times more efficient than in a control sample of cervical tissue.

**2. Status of Clinical Trials:** Three randomized controlled trials (RCTs) are being conducted in Kenya, South Africa, and Uganda to systematically assess whether circumcision of adult males protects against

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<sup>1</sup> ABC stands for: A - Abstain (or delay among youth); B - Be faithful (or reduce partners); and C - Condoms (especially correctly and consistently). Current evidence indicates that a balance of all three is optimal for the most impact. Despite earlier doubts about the feasibility of changing sexual behavior, it is now clear that many people (both younger and older) will abstain or reduce partners in the face of a life-threatening epidemic. Another component sometimes added is "D" for drugs, which refers both to intravenous drug use and recreational drugs such as alcohol that can increase the possibility of unsafe sex. The key concept is to support all the components in a balanced, supportive way. Jim Shelton, USAID Office of Population and Reproductive Health "Contraceptive Pearl," 7/25/2002.

HIV. These trials, designed to detect a minimum 50 percent reduction in HIV risk, should provide definitive evidence regarding the efficacy and safety of MC within three to five years.

**3. Acceptability Studies:** Quantitative and qualitative acceptability studies conducted in preparation for the Kenya, South Africa, and Uganda RCTs, and at least half a dozen other studies in these and four other African countries, indicate that many men as well as women show favorable attitudes towards MC. For example, of over 800 men and women interviewed in Botswana, 68 percent expressed interest in having their male child circumcised, and a similar proportion of uncircumcised men expressed interest in becoming circumcised. In Zambia, where MC is relatively uncommon (and where USAID is planning to support the development of pilot MC services), preliminary qualitative data indicate there is widespread interest as well.

**4. Field Introduction Studies:** A basic field introduction study in Siaya, western Kenya, recently demonstrated the feasibility of introducing MC services in rural and peri-urban Ministry of Health (MOH) facilities in an area where MC is not traditionally practiced. In order for MC to be introduced, however, clinicians must be trained, proper instruments and supplies must be made available, and informed consent procedures and HIV/STD counseling mechanisms must be in place. In Chogoria, central Kenya, where MC is traditionally practiced, a hospital-based MC program has developed an in-depth preventive health education initiative for adolescent boys. The initiative is a culturally sensitive adaptation of the traditional one- to two-week period of seclusion following MC. If further adopted, this approach may have the potential to reach a large number of adolescent boys in Kenya.

**5. Areas of Concern:** Safety and quality of care for MC, especially pre- and post-operative care and asepsis, are of key importance. There is a dearth of accurate data on complication rates in both traditional and clinical settings. Bioethical concerns must be addressed and cultural self-determination must be respected to avoid the perception that the practice is imposed through cultural hegemony. There is an urgent need to address possible behavioral “disinhibition” for those men who are already being circumcised in traditional and clinical settings, even before the RCT findings are announced.

Seven topic areas were suggested as a framework for conclusions and recommendations:

**1. Locality and Context:** MC programs will only be successful if they are country- or region-specific and are implemented with regard for national and local laws and cultural and religious norms. It is not necessary to wait for the results from RCTs to start learning about the potential applicability, acceptability, and feasibility of developing MC services in local environments.

**2. Policies, Regulations, and Guidelines:** Improvement or expansion of MC services will require a review of policies and regulatory frameworks at national levels.

**3. MC Information Dissemination:** Current knowledge on MC must be disseminated to the public in a careful and planned manner so as to avoid mixed messages. Stakeholders must be consulted now to build the constituencies needed to support MC, should the RCTs demonstrate a protective effect.

**4. Clinical Management Protocols/Guidelines:** Standardized MC guidelines are needed for both clinical and counseling procedures to ensure quality MC services.

**5. Program Design:** Program design needs to be developed now in anticipation of possible future scaling-up of MC services.

**6. Costs and Resources:** Costs and resources need to be anticipated and secured to ensure equity in access and quality of services for all potential clients.

**7. Ethical Concerns:** An in-depth assessment of the ethical considerations related to MC is needed to ensure informed choice and consent.

### **Key Conclusions and Recommendations:**

- Male circumcision should not be actively promoted for HIV prevention unless and until the RCTs confirm MC to be effective in reducing HIV infection. However, it is not necessary to wait for the RCT results to begin developing the required infrastructure for providing safe and affordable MC services.
- A holistic, culturally adapted approach should be considered for both traditional and clinic-based MC so as to promote the “ABCs” of prevention, family planning and reproductive health, and related primary prevention messages.
- Additional observational studies are needed to better understand traditional practices.
- Practitioners may need training to improve the quality of care for existing MC services.
- There is an urgent need for more data on the safety of MC in both traditional and clinical settings. USAID plans to support pilot projects offering safe MC services not as an HIV prevention service but as part of general services for male hygiene and reproductive health.
- Male circumcision as a potential HIV prevention measure would not be a major priority where HIV prevalence rates are low or where HIV/AIDS is contracted primarily through other modes of transmission (e.g., receptive anal intercourse or injecting drug use).

### **Other Recommendations:**

- Female genital cutting (FGC) must be de-linked from MC; it is possible to recognize that FGC is a harmful practice while acknowledging that MC has potential health benefits.
- Neonatal MC services might be considered within the context of programs to reduce mother-to-child HIV transmission, such as is being considered in Haiti and Zambia.
- Studies are needed to assess disinhibition, not only in the context of RCTs but also among men where MC is currently the norm.

## Day 2 Meeting

Day 2 involved a smaller working meeting attended by 29 people, including several of the Day 1 technical experts and representatives from USAID cooperating agencies that have initiated circumcision-related field activities. The group explored the feasibility of further activities, including research (e.g., safety and complication rates, acceptability, etc.), dissemination of the existing data on risks and benefits of circumcision, and possible introduction of pilot clinical services.

### Conclusions and Recommendations From Day 2 Included:

- Rapid assessment and introduction studies should be implemented in some high HIV prevalence countries where MC is not practiced by the majority of men (e.g., Zambia, South Africa, and Haiti). MC introduction should be supported in areas such as Kwa-Zulu/Natal, South Africa, in a manner similar to Kenya's programs in Siaya District and at Chogoria Hospital. These rapid assessments should be facilitated by sharing existing protocols and data collection instruments developed by the RCT and other MC investigators.
- A prospective multisite study of complication rates for MC (both traditional and clinical) should be conducted among adults and neonates in the countries where RCTs are underway (Kenya, Uganda, and South Africa). Zambia, Haiti, Cameroon, and Botswana were also mentioned as possible sites. Over the next few months a concept paper will be developed by meeting participants.
- A rapid assessment should be conducted of the recently developed MC School program and curriculum in the Eastern Cape area of South Africa. A concept paper will be written to seek institutional support for an assessment of surgical techniques, complication and safety issues, training and curriculum methodologies, etc. This might include bringing in experts to help ensure integration of MC and male cultural initiation approaches such as "responsible manhood" initiatives, the "ABCs," family planning, etc. A similar evaluation is recommended for Chogoria Hospital's "Seize the Day" safe MC/ young male acculturation program.
- Along the lines of the three RCTs in Kenya, Uganda, and South Africa, the sites for introducing MC as a male RH service (Zambia, South Africa, Haiti) should communicate with one another to assure some comparability and share lessons learned, best practices, etc.
- JPHIEGO will host an MC technical working group to review and compare surgical and other medical procedures, medical devices, and guidelines for adolescent and adult MC. WHO and other key organizations will be invited to participate or co-host such meetings.
- Based in part on the experience with the Siaya MC introduction project, a cost-effectiveness study should be conducted to estimate the costs of program scale-up and sustainability.
- Work with the media to ensure more balanced and accurate press coverage of MC issues.

## 1.0 Day 1

### Welcoming Remarks: Dr. Anne Peterson, USAID Assistant Administrator for Global Health, and John Berman, AIDSMark Director

*Dr. Peterson noted that new findings are often controversial. The first data linking male circumcision to reduced HIV transmission date back to the late 1980s. At that time there were concerns that this might be an ecologic association confounded by unknown factors. The last decade has seen a multiplicity of additional studies that show a very strong, consistent association even when controlled for all confounders -yet MC is still a controversial intervention. We need together to decide the next research and action steps.*

*John Berman expressed thanks to the conference organizers and outlined three overall objectives for the conference:*

- 1) Reach a consensus on the epidemiological and cultural acceptability data*
- 2) Develop priorities for pilot programs related to MC*
- 3) Develop shared and realistic expectations for what can be accomplished while remaining cognizant of the potential problems inherent in this area*

#### Rationale/Statement of Objectives for the Meetings

Over the past 15 years, 35 studies from 10 countries, mostly in Africa, have found a significant association (a two- to eightfold greater risk) between HIV risk and lack of male circumcision, as reviewed in *The Lancet* (<http://hivinsite.ucsf.edu/InSite.jsp?doc=2098.4613>). A UNAIDS multisite study that investigated numerous behavioral and other potential factors for the pervasive disparities in HIV prevalence across different African regions [1] found lack of circumcision (and genital herpes, which is more common in uncircumcised men) to be the principal determinant for these large and continuing disparities.

The meetings on male circumcision held in Washington, D.C., on September 18-19, 2002, involved an intensive exchange of information, analysis, and experience among individuals interested in the procedure as a potential prevention tool against HIV/AIDS. The meetings were attended by policy and field staff from USAID Missions, NGOs, USAID cooperating agencies, other multilateral and donor agencies such as UNAIDS, UNICEF, WHO, NIH, and CDC, and other stakeholders.

The goals of the meeting were to:

- Present existing and emerging epidemiological and biological data on MC, findings from recent and ongoing MC introduction studies, and findings from prospective clinical trials supported by NIH/CIHR, the French government, USAID, and the Gates Foundation.
- Present and discuss MC policy and implementation issues to achieve consensus on when, how, and for whom to develop MC service programs.
- Address key concerns and caveats related to bioethics, informed choice, behavioral “disinhibition,” cost-benefit analysis, introduction within ongoing reproductive health programs, and coordination with female genital cutting eradication programs.
- Identify other research and program priorities for future MC assessment and introduction activities.

# 1.1 Evidence: Epidemiological and Biological Findings

**Moderator: David Stanton, Director, Research and Technical Division, USAID Office of HIV/AIDS**

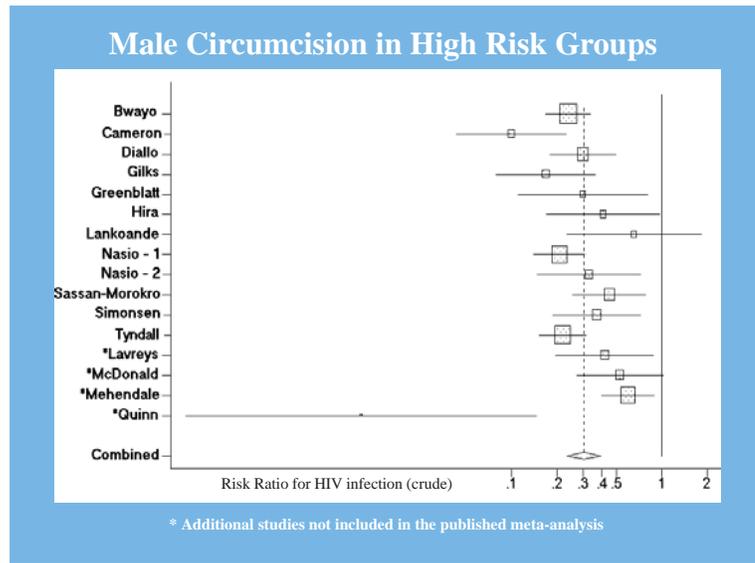
David Stanton introduced the presenters by noting that since the mid- to late 1980s, research on MC as a risk factor in HIV transmission has gained increasing credibility, resulting in an attitudinal shift within the epidemiological research community.

**Presenter: Dr. Helen Weiss, London School of Hygiene and Tropical Medicine**  
**Topic: Update of current epidemiological evidence on MC and HIV transmission**

Sub-Saharan Africa has been particularly hard hit by HIV/AIDS, especially in the south and east of the continent. HIV prevalence is over 20 percent in the general adult population in seven countries in southern Africa. Among infected adult men, it is estimated that 90 percent have contracted the infection through heterosexual intercourse.

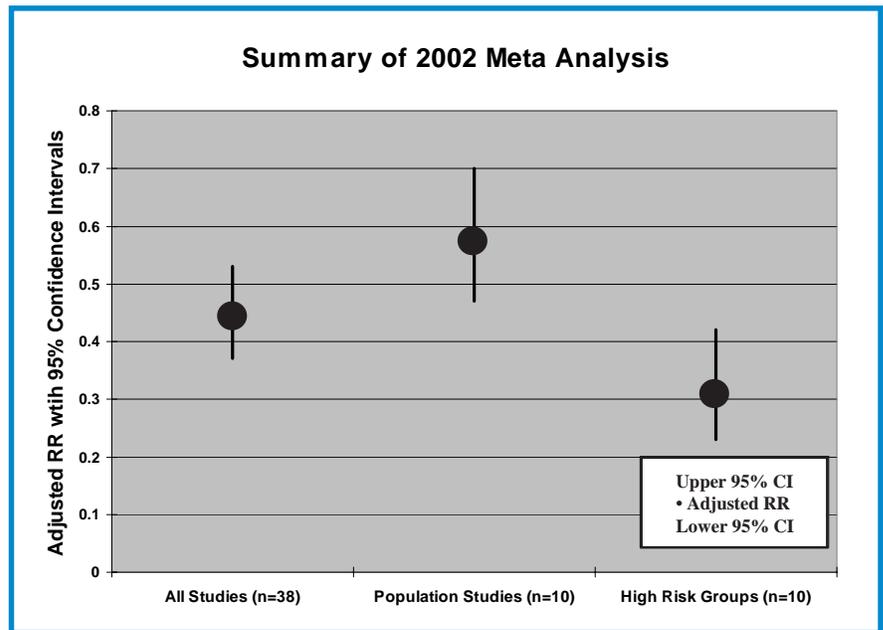
An estimated 30 percent of African men in traditional societies are not circumcised. In the late 1980s, mapping of the HIV epidemic demonstrated a strong correlation between areas with high levels of HIV infection and areas with low rates of circumcision [2]. Although such an ecological correlation may be the result of confounding, this finding warranted further attention.

In 1999, the London School of Hygiene and Tropical Medicine undertook a systematic review of the evidence [3]. The inclusion criteria for this meta-analysis limited the review to published studies (up to April 1999) from Africa of female-to-male transmission of HIV-1. Results of the 28 studies found that circumcised men were less than half as likely to contract HIV. This correlation was particularly strong among high-risk groups (adjusted risk ratio (RR) for seven studies: 0.29; 95% CI 0.20-0.41). An updated meta-analysis was conducted in September 2002, which expanded the number of studies and also included high HIV prevalence non-African countries. The 10 additional studies, including five additional cohort studies and two non-African studies, resulted in a total of 38 studies, 22 having been adjusted for confounding variables. The results of the updated analysis were consistent with the initial study. The adjusted RR was strongest among the populations at high risk (adjusted RR=0.31; 95% CI 0.23-0.42). There was also a significant protective effect in the population-based studies (adjusted RR=0.57; 95% CI: 0.47 - 0.70).



As with any meta-analysis of observational studies, these results do not prove that male circumcision protects against HIV. However, the studies showed a strong and consistent relationship, and cohort studies, which are less susceptible to biases and are able to account for changes in HIV incidence, produced similar or stronger results. In almost every study, the effect was strengthened when adjusting for confounders, making it unlikely that the overall effect was due to residual confounding. Perhaps the most

striking finding was reported by Johns Hopkins researchers working in Rakai, Uganda, who analyzed risk factors for HIV infection in married couples where only one partner was initially infected [4]. Among 137 uncircumcised, uninfected men at baseline, 40 seroconverted during the approximately two-year follow-up period. Among the 50 circumcised men (including 14 non-Muslims), none became infected during the same period regardless of their female partners' viral load levels.



There are few data on the association between male circumcision and male-female transmission of HIV. This potential relationship is difficult to tease out largely because women may have various partners. In the same prospective study of serodiscordant couples from Uganda, circumcised men were significantly less likely to transmit HIV to their female partners [5]. In Brazil, however, a cross-sectional study based on infection rates in women and their report of male partners' MC status found no association [6]. Additional data are needed.

Also important to examine is the relationship between male circumcision and other STDs. Circumcision appears to lower the risk of contracting genital ulcer diseases (GUD) such as chancroid, herpes simplex virus (HSV-2), and syphilis. Furthermore, circumcised males are at much less risk for penile cancer [7], and there is increasingly convincing evidence that circumcision helps protect women against cervical cancer [8]. It is important to disseminate the current evidence and continue studies into the acceptability and feasibility of MC in non-circumcising populations with high HIV incidence. Moreover, researchers and programmers must assess the safety of current circumcising procedures and develop affordable services for safe, voluntary MC. Finally, educational materials conveying the message that MC may reduce, but not eliminate, the risk of HIV infection must be developed and disseminated.

*The studies showed a strong and consistent relationship, and cohort studies, which are less susceptible to biases and are able to account for changes in HIV incidence, produced similar or stronger results. In almost every study, the effect was strengthened when adjusting for confounders, making it unlikely that the overall effect was due to residual confounding.*

*It is important to disseminate the current evidence and continue studies into the acceptability and feasibility of MC in non-circumcising populations with high HIV incidence.*

In addition, it is important to remember that MC as a potential AIDS prevention measure should not be a priority where HIV prevalence rates are low or where HIV is contracted primarily through other means (e.g., homosexual intercourse or injecting drug use).

**Presenter: Dr. Bruce Patterson, Northwestern University, Chicago, Ill.**

**Topic: Recent research on the physiology and uptake of HIV in the human foreskin**

Much research has been done on the cervix, and more recently on the foreskin, to assess the hypothesis that susceptibility to sexual transmission of HIV-1 is a function of the presence of major HIV-1 target cells (CD4+ T cells, macrophages, and Langerhans' Cells) and certain HIV-1 co-receptors such as chemokine receptors CCR5 and CXCR4, as well as STDs.

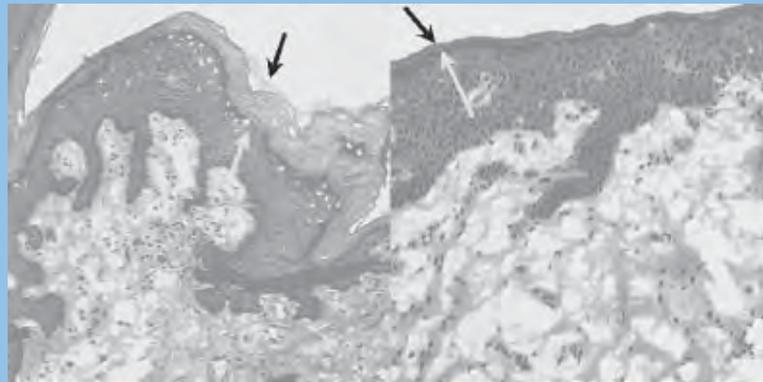
Recent research on the foreskin stems from the following findings with the cervix. The cervix offers three barriers to male-to-female HIV transmission: 1) cervical/vaginal secretions; 2) epithelial barriers, which vary dramatically between the cervix and the endocervix; and 3) the number and type of HIV-1 target cells, as well as the presence of certain flora and STDs. Certain types of cells, as well as the presence of HIV-1 co-receptors, are associated with HIV-1 infection of the cervix. A significant mathematical correlation has been found between HIV-1 infectivity and the CCR5 HIV1 co-receptor. In addition, hormonal influences (progesterone, for example) may also affect the HIV-1 susceptibility of the cervix through shifts in the types of co-receptors.

Influences of co-receptors on HIV-1 susceptibility are very different in different populations. Types of HIV-1 co-receptors appear to vary by region. Co-receptors (CCR5) found in cervical tissue samples of women in Chicago were much more common than in samples from women in Ethiopia, where CXCR4 was more common. The presence of HIV-1 co-receptors is associated with exposure to STDs. There is a need to model microbicide interventions for the cervix based on different levels and types of co-receptors. Researchers are looking into the hypothesis that the human papilloma virus (HPV) may make HIV worse (the reverse was analyzed previously). The presence of certain types of HPV (HPV E7) may increase HIV-1 infectivity through the expression of HIV-1 co-receptors. Recent studies indicate dramatic (up to 32-fold) elevation of HIV-1 infection in cervical cells in the presence of certain types of HPV. Treatment of STDs such as trichomoniasis appears to reduce infectivity, supporting the long held recommendation to aggressively treat STDs to lower HIV incidence.

A newly developed method permits the growth of cervical and foreskin tissue in explant culture for up to seven days. This permits the evaluation of the relative susceptibility of foreskin and cervical tissue to HIV-1 infection [9]. This system maintains the integrity of the specimens, so that the epithelium can be exposed to HIV-1 and assays conducted below this tissue layer to assess the relative infectivity of different locations on the cervix and foreskin. Harvesting cultures and performing molecular observations assesses susceptibility to HIV-1. Using this method, HIV-1 infection of T-cells can be observed within six hours, in Langerhans' cells at 24 hours, and with an abundant infection in these by 96 hours.

The foreskin has a similar make-up to the cervix – both have squamous cells. But the relative susceptibility of different parts of the foreskin (internal versus external foreskin) differs from the cervix (epithelium versus endocervix). The number of HIV-1 target cells in the internal foreskin is much higher than in the cervix or other parts of the penis. There are dramatic keratin differences between the internal and external surfaces of the foreskin. The internal foreskin is a truly mucosal surface, whereas the external foreskin is much like a regular skin surface. In addition, Professor Roger Short [10] recently shared results suggesting that Langerhans' cells - key HIV-1 target cells in the internal portion of foreskin – may be closer to the surface in the epithelium.

## Comparison of Keratin Thickness on the External and Mucosal Surfaces of Human Foreskin



External Surface

Mucosal Surface

It is difficult to infect specimens of external foreskin with HIV-1. Samples of the external foreskin, which has few HIV-1 target cells and greatly increased keratinization compared to internal foreskin, showed no detectable HIV-1 DNA in the outer surface. Compared to the cervix, the internal foreskin samples were found to contain significantly (five to ten times) higher levels of HIV-1 target cells, macrophages, and co-receptors. There is an age-related increase (which eventually drops off) in the number of target cells in the foreskin. There is also an association of HIV-1 target cells with exposure to STDs, which is consistent with the observed greater HIV infectivity associated with STDs.

*Compared to the cervix, the internal foreskin samples were found to contain significantly higher levels of HIV-1 target cells, macrophages, and co-receptors.*

*Adult foreskin mucosa appears to be much more susceptible to HIV infection than cervical mucosa or the external surface of the foreskin. HIV uptake in the inner foreskin tissue samples is up to nine times more efficient than in samples of cervical tissue.*

Adult foreskin mucosa appears to be much more susceptible to HIV infection than cervical mucosa or the external surface of the foreskin. HIV uptake in the inner foreskin tissue samples is up to nine times more efficient than in samples of cervical tissue. One important limitation in these findings is the absence of data for skin samples from the frenulum and penile shaft of uncircumcised men. Preliminary data from Szabo and Short, based on tissue samples from deceased men, suggest that there is no significant difference between circumcised and uncircumcised men in the keratinization of the glans penis.

Based on these findings and the new methodologies available, there should be an aggressive push to assess potential use of microbicides in non-circumcised males. The transplant culture system can evaluate up to 24 specimens per day; and it is quite feasible to quantify how compounds might influence HIV-1 susceptibility for uncircumcised men. The option of circumcision in high-risk populations needs to be considered, as the foreskin appears to be an important reservoir for HIV. Specific questions regarding foreskin removal, such as how much to remove and where the highest density of cells is found, remain undetermined.

## 1.2 Status of Current Clinical Trials (and Related Acceptability Findings)

**Moderator: Dr. Edward Tramont, Director, Division of AIDS (DIAIDS), NIAID/NIH**

*Dr. Tramont noted that as of 2002 the HIV/AIDS epidemic remains unabated and there is limited progress toward a vaccine. Two promising strategies to slow the epidemic are microbicides and male circumcision. The recent findings of RCTs with hormonal replacement therapy demonstrate, however, that the results for MC in observational studies must be verified with appropriately designed clinical trials.*

The three existing RCTs designed to assess whether circumcision of adult males protects against HIV should provide definitive evidence regarding the efficacy and safety of adult MC. The trials are being conducted in Kisumu, Kenya (**Robert Bailey**, University of Illinois at Chicago, principal investigator); Johannesburg, South Africa (Adrian Puren, South Africa National Institute of Communicable Disease, and **Bertran Auvert**, University of Paris, principal investigators); and Rakai, Uganda (**Ronald Gray**, Johns Hopkins University, principal investigator). The Kenya and South Africa trials have already begun enrolling volunteers. In Uganda, a pilot study is about to begin, and the main trial will begin enrollment thereafter. In all three settings the acceptability of MC and reported willingness to be circumcised is high. Findings from the three trials are expected within three to five years.

RCT acceptability findings were presented for Kisumu, which is predominantly made up of the non-circumcising Luo ethnic group. An estimated 10 percent of Luo men are circumcised. Approximately 60 percent of Luo men and women interviewed would prefer to be circumcised or have a circumcised partner. Among 18- to 25-year-old males, 86 percent said they would prefer to be circumcised. Acceptability findings from Rakai, based on interviews with 1,178 uncircumcised men, found that

*Approximately 60 percent of Luo men and women interviewed would prefer to be circumcised or to have a circumcised partner. Among 18- to 25-year-old non-circumcised males, 86 percent said they would prefer to be circumcised.*

60 percent would accept MC and enroll in a RCT, even if MC were delayed. Acceptance was highest (65 percent) among the 20- to 29-year age group. Results from focus group discussions showed that participants found MC acceptable for reasons of health and hygiene. They had little concern about its religious connotations, and women prefer circumcised men as partners. MC acceptability was also reported to be high in the Johannesburg, South Africa, trial area, where MC prevalence is 21 percent.

The design of each trial is similar. Uncircumcised adult men who are medically eligible and provide informed consent will be randomly selected for circumcision and control arms. All study participants will be extensively counseled on ways to prevent HIV infection, including abstinence, mutual monogamy, and consistent condom use. They will be provided with condoms and encouraged to seek prompt treatment for suspected STDs. HIV and STD incidence will be assessed periodically in both the circumcision and control groups for approximately two years. All participants randomized into the control arm are offered free circumcision at the end of the trial. All three trials are designed to assess the hypothesis of a minimum 50 percent reduction in the incidence of HIV infection relative to HIV incidence in uncircumcised men.

## Rakai Acceptability Studies

- **Interviews with 1178 uncircumcised men:**
  - \*60% said they would accept circumcision and be willing to enroll in a RCT, even with delayed circumcision
  - \*Acceptance highest in 20-29 age group (65%)
- **Focus Groups:**
  - \*Circumcision acceptable for health/hygiene
  - \*No concerns about religious connotations - “Jesus was circumcised”
  - \*Women prefer men to be circumcised

### Differences in study design among the three trials:

**Kenya:** Men testing HIV positive at baseline are not eligible for this trial. When men test positive, they are referred to support groups and other care and support services available in the community. The study will recruit 1,338 men in each arm with an expected decreased annual incidence from 2.5 percent to 1.25 percent. As of mid-September 2002, 1,245 men age 18 to 24 years old had been screened. Of those, 97 percent consented to HIV testing (11 percent tested positive; 5.4 percent in ages 18 to 20 and 15.3 percent in 21- to 24-year-olds) and 662 have been randomized. NIH and CIHR (Canadian Institute for Health Research) are funding this trial.

**Uganda:** The Uganda trial actually consists of two separate trials. The first, funded by the NIH, will enroll 5,000 uncircumcised, HIV negative men into two arms with an expected decrease in incidence from 1.8 to 0.9 per 100 person-years. A separate study, funded by the Bill and Melinda Gates Foundation, will enroll approximately 800 uncircumcised HIV positive men and randomly divide them into circumcision and control groups, in order to assess the effect of MC on transmission to female partners as well as the safety of performing MC in HIV positive men. An initial six-month pilot study will include 200 HIV negative men and approximately 50 HIV positive men with randomization into immediate versus delayed MC after 24 months. At the end of both trials, men in the control group will be offered free circumcision.

**South Africa:** Both HIV positive and HIV negative men are eligible to participate. Private general practitioners, who have prior experience with MC services, have been trained to perform the procedure using a common protocol developed by the Urology Department of the University of Witswatersrand. The trial will seek a total of 3,500 participants divided evenly into two arms. HIV incidence of 2.2 percent per year is expected to fall to 1.1 percent per year. The trial began in August 2002 and currently averages about 10 randomizations per day. The Government of France is funding this trial at the relatively modest cost of \$700,000.

## 1.3 Field Research on Acceptability and Feasibility of Introducing MC Services

**Moderator: Dr. Daniel Halperin, Senior Technical Advisor, USAID Office of HIV/AIDS**

*Dr. Halperin reported that there have been at least nine surveys or qualitative studies on MC acceptability in Africa. These include studies in Botswana, Kenya, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe. In virtually all studies, a majority of respondents expressed interest in MC. [11-20]. A Malawi study is planned in mid-2003.*

**Presenter: Tom Onyango, Kenya MOH**

**Topic: Trial intervention of MC services in Nyanza Province, Kenya<sup>2</sup>**

The Siaya project is a trial intervention of MC services in Nyanza province in western Kenya, which has the country's highest adult HIV prevalence rate, between 28 and 35 percent in different studies. Prevalence in Siaya is 38.4 percent. The province is populated by the Luo, the only major ethnic group in Kenya that does not traditionally practice MC. About 90 percent of Luo men are not circumcised [21].

Despite the absence of traditional circumcision, an acceptability study conducted in 1998 showed that the Luo community has positive views about MC. More than 75 percent of Luo men and women equated MC with greater cleanliness and reduced risk of STDs. More than 50 percent believed that circumcised men enjoy sex more and give greater sexual pleasure to their partners. Approximately 60 percent of Luo men and women said they would prefer to be circumcised or to have a circumcised partner. Seventy-four percent of men and 88 percent of women said they would circumcise their son if affordable and safe services were available.

Few clinicians in the district have had comprehensive training and experience in conducting MC. The planned intervention had the following five objectives:

- 1) Increase the number of health providers trained to perform safe MC
- 2) Increase the numbers of circumcisions among males over 8 years old
- 3) Increase the knowledge of health providers about the risks and benefits of MC
- 4) Increase the availability of MC instruments and supplies in 20 facilities
- 5) Develop consistent policies and practices regarding MC pricing

Twenty-six male clinicians were trained to provide MC, and informed consent procedures were developed. Education on the risks and benefits of MC was conducted in 120 schools, 10 churches and 15 administrative fora. Informational brochures and a poster were developed and distributed in schools and other sites. Twenty facilities were selected and provided with instruments and supplies.

After six months, activities in Siaya were compared with Nyando, a control area. Interviews with clinicians showed significant differences between the two sites in the number of circumcisions performed, and the percentage of clinicians that recommended the procedure to more than five clients. Peak months for MC were August and December, when more than 100 procedures per month took place in Siaya. The

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<sup>2</sup> As the key investigator for the Siaya intervention, Tom Onyango Matinde of the Kenya Ministry of Health made a presentation on behalf of his co-authors Dr. Richard Muga (Director of Kenya Medical Services), Dr. Robert Bailey (University of Illinois at Chicago), and Dr. Rudi Poulussen (Belgium Development Corp.).

modal age range for MC was 20 to 24 years, but there were some procedures performed on men above age 40 and on children. During the intervention's first 25 months, only 24 MCs in the control district were reported, while 433 MCs were performed in the Siaya District.

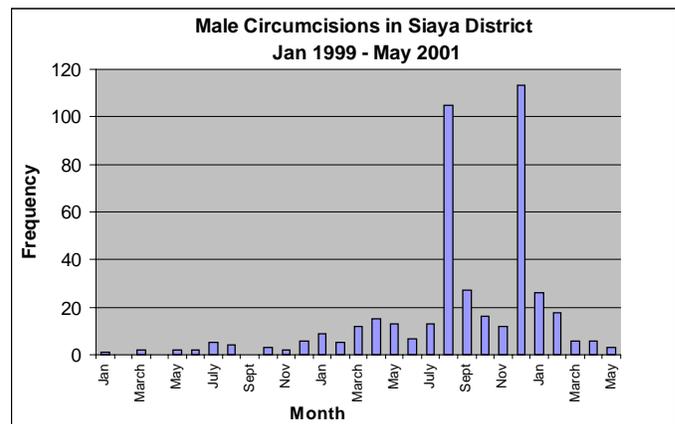
Cost was the most important factor in determining the number of men who requested MC. The initial charge of 250 Ks, or about US \$3, appeared to be too expensive. The cost was reduced to 100 Ks, or about US \$1, which attracted many more clients. There was a high rate of patient satisfaction. Some men came for medical or cosmetic reasons, including genital warts. It was not possible to accurately

evaluate the rate of complications. There were anecdotal reports of bleeding and infection, which were appropriately treated. Although many people thought that circumcision would not be acceptable among a non-practicing group such as the Luo, the opposite proved true. By giving people clear information, they were able to make their own choice. The intervention was done on a very small budget (less than US \$15,000), financed initially by the Belgium Government.

*Although many people thought that circumcision would not be acceptable among a non-practicing group such as the Luo, the opposite proved true. By giving people clear information, they were able to make their own choice.*

This experience shows that before MC can be offered, clinicians must be trained, proper instruments and supplies must be made available, and informed consent procedures and HIV/STD counseling mechanisms should be in place. There is still a substantial need for more data on rates of complications in clinical settings.

## Trial Intervention Results from Nyanza Province, Kenya



**Presenter: Dr. Judith Brown, Nazareth Hospital, Kenya**

**Topic: Integration of traditional and clinical circumcision in Chogoria Hospital, Kenya**

In most ethnic groups in Kenya, MC is practiced as part of a male rite of passage. It includes a post-MC traditional period of seclusion of up to several weeks, in which boys are taught about the community's expectations of men, relationships with women, potential wives and children, and sexual activity, which (among some groups) is expected to begin soon after healing. Teaching methods often include beatings, harsh language and rote learning.

Among the Meru ethnic group of Central Kenya, where MC occurs on average about age 15, several different traditional techniques of circumcision are practiced. By undergoing MC, a child is "made into a man," and is expected to undergo physical, psychological, social, and sexual transformations. A program at Chogoria Hospital, a church-affiliated hospital established in 1922, combines clinical MC with a hospital-based period of group seclusion and teaching [22]. Although some boys are circumcised in groups by traditional practitioners, other families have their sons circumcised at the hospital or at home individually. Since these boys miss out on the opportunity for the teaching and peer bonding that occurs during traditional group seclusion, Chogoria Hospital now offers a group seclusion and training period within the hospital where boys learn some traditional cultural material as well as about reproductive health in general, HIV/

AIDS, drug and alcohol abuse, goal-setting, making responsible choices, family planning, abstinence and faithfulness, violence, and so forth. Groups of 20 to 30 boys are housed in a special ward for five to seven days following the circumcision. The expectation that MC is performed at a time when boys can learn the ways of men provides an opportunity to build on traditional customs, create more gender-equitable behavior, and establish healthy attitudes and practices early in life. The Chogoria Hospital work is relevant to the “ABC” approach and adapts Meru traditional initiation/MC teachings to modern circumstances.

*The expectation that circumcision is performed at a time when boys can learn the ways of men provides an opportunity to build on traditional customs, create more gender-equitable behavior, and establish healthy attitudes and practices early in life.*

Other African ethnic groups could also re-examine their traditional MC practices and teaching. Since circumcision is a time when boys are expected to learn the ways of men, it is an opportunity to build on traditional customs, create more gender equitable behavior, and establish healthy attitudes and practices early in life.

## Other Survey and Qualitative Data on MC Acceptability

**Presenter: Steve Hodgins, USAID, Zambia**

**Topic: Findings from focus groups in Lusaka and a nearby rural area in Zambia**

The HIV prevalence rate in Zambia is approximately 16 percent in adults. About 17 percent of men in the country have been circumcised (2000 DHS). Male circumcision is not traditionally practiced outside of some areas in the Northwest (e.g., Luvale) region. Focus group discussions were held with urban and rural men to assess MC practices, opinions, and acceptability among married and unmarried men ages 18 to 39. Most of the participants were not circumcised. Among groups traditionally practicing MC, not being circumcised was associated with uncleanness, premature ejaculation, and unfitness for marriage. MC is viewed as a milestone for manhood, protection from disease, and an enhancement for women’s sexual pleasure as circumcised men are thought to be able to “perform” longer, thereby increasing their female partner’s satisfaction. Among groups not practicing traditional MC, the men expressed limited interest in MC although some informants said they wished they had been circumcised because there was a common belief that women prefer circumcised men. Male circumcision was also associated with reduced risk of STDs, including HIV. Several participants said they were seriously considering the procedure.

The reported age of MC was generally between 8 and 15 years old. Performing circumcision on a boy less than 5 years old was considered unsafe. There were mixed views on infant MC. Some felt that the procedure would not be as painful early in life, and that if done later during adulthood, healing would be slower and complications more likely. There were also mixed views on traditional versus medical MC. Groups practicing MC tended to prefer camp settings, which offer community members an opportunity to pass on the group’s traditional values to the boys. Urban men were less confident in the safety of traditional MC; non-practicing groups preferred hospital-based services for safety reasons. They were concerned about the reuse of blades and disease transmission.

*Respondents did not raise concerns that MC could compromise male sexual satisfaction. There was a view that MC made condom use easier.*

Practicing and non-practicing groups claimed MC is a protective factor against STDs since the procedure tends to make the penis “harder and drier.” They believe that transmission of STDs and HIV occurs through the glans and that with the foreskin intact, the virus could be harbored. A few informants viewed MC as a “natural condom” conferring 100 percent protection, and one claimed that if he was circumcised, he couldn’t possibly get HIV. Most men considered such kind of protection as only partial. Some believed that MC is less effective in preventing HIV than for other STDs. Nevertheless, these perceptions are troubling since they suggest that circumcised men might not find it necessary to practice safer sex.

Respondents did not raise concerns that MC could compromise male sexual satisfaction. There was a view that MC made condom use easier. The concerns around safety included fear of disease transmission by using the same knife on several boys. Hence, boys now frequently arrive with their own razor blades for the procedure. Slow healing, localized infection, blood loss, and risk of dying were also mentioned as concerns. Expense is perceived as a barrier, both for traditional MC camps and medical MC. There are few clinicians trained to practice MC. Some informants reported trying unsuccessfully to obtain medical MC.

A key informant interview was also held with a Lusaka-based physician who is originally from an MC-practicing ethnic group. He performs MC on weekends on a volunteer basis and his clientele consists largely, but not exclusively, of men from MC-practicing groups or men who have intermarried with MC-practicing groups. He sees a slow increase in demand for MC from other groups and reports interest among medical colleagues in offering these services.

In conclusion, although MC is relatively uncommon in Zambia, there appears to be widespread and evidently growing interest. Focus group discussion participants were interested in more information. There is a need for and interest in acceptability and feasibility studies. There are potential partners on the ground but relatively few trained physicians. There is a need to examine the regulatory environment and whether other practitioners can perform the procedure.

**Presenter: Dr. Daniel Halperin, Senior Technical Advisor, USAID Office of HIV/AIDS**  
**Topic: Recent findings from Botswana (Harvard AIDS Institute) and Harare (University of California, San Francisco) surveys and Southern Africa qualitative data**

**MC Acceptability in Botswana:** In Botswana, which has the world’s highest rate of HIV infection, MC was universally practiced some 100 years ago. The practice is now much less common, however. Roger Shapiro (Botswana-Harvard AIDS Institute Partnership) and colleagues from the Botswana MOH and the University of Botswana conducted a cross-sectional survey in the spring of 2001 with 605 men and women aged 18 or over in various geographic and ethnically representative locations throughout the country [13, 14]. Of men and women approached at meeting places and public markets, 57 percent agreed to participate. The survey consisted of a baseline questionnaire followed by an informational session on the potential risks and benefits of MC. A second set of questions was administered following the information session. Prior to the information session, 68 percent of respondents said they would definitely or probably circumcise a male child if MC was offered free of charge in a hospital; this increased to 89 percent following the informational session. Of 316 men, 238 (75 percent) reported they were not circumcised. Of these uncircumcised men, 61 percent said they would definitely or probably be circumcised

*Among the uncircumcised men, 61 percent said they would definitely or probably be circumcised if services were available in a safe hospital setting, free of charge. This increased to 81 percent after a brief informational session.*

if MC services were available in a safe hospital setting, free of charge. This increased to 81 percent after the informational session. The majority of respondents favored MC at age 5 or younger. Given that most births in Botswana occur at district hospitals, it may be feasible to implement infant MC services. Parents should be offered the option of MC for young children and it should also be an option for adults and adolescents, especially if RCTs confirm that MC has a protective effect against HIV.

**MC Acceptability Research in Zimbabwe:** In 2000 Catherine Fritz, Daniel Halperin, and colleagues from the University of California, San Francisco, and the University of Zimbabwe Medical College conducted a survey of 200 men randomly sampled from beer hall settings in Harare [17]. Of these, 14 percent self-reported being circumcised. Of the remaining uncircumcised men, 45 percent said they would like to be circumcised if it were affordable and performed safely.

**Qualitative Acceptability Research in South Africa:** Eight focus group discussions were conducted by Dr. Halperin in 2001 with men and women in the Johannesburg area and in Kwa-Zulu/Natal, South Africa, where HIV prevalence is very high and MC has not been practiced since the early 1800s [18,20]. Among 52 men interviewed, seven were circumcised. Of the remaining 45 young men, 41 (including 31 of 32 Zulus) said they would be interested in MC. Most said they would prefer that the procedure be performed at a private practitioner's office rather than at a free public clinic. Two young men had foreskin complications; one claimed he had never been able to have sex because his foreskin would not retract at all.

The men overwhelmingly stated they prefer MC because they believe it promotes better hygiene. They spoke of difficulties in staying clean, of not “smelling,” and of not contracting infections. All 16 women interviewed said they would prefer a circumcised male partner. Male circumcision was thought to make it easier to use a condom, as the uncircumcised foreskin can get “caught up” in a condom. Some men said they have had to remove condoms because of discomfort in the foreskin. A couple of men believed that MC would protect them from HIV. These statements provoked loud arguments from other participants, who admonished that “if you're with someone who has AIDS, you'll get it too, MC or not.”

### Some Participant Questions:

*Is informed consent given by the boy or by his parents?*

In central Kenya, at Chogoria Hospital, generally the parent who approves the procedure accompanies the boy. In Western Kenya, if the client is under the age of 18, he must have a parent's consent. If done on infants, as in Cameroon, a parent gives consent.

*Are providers other than medical doctors being trained to do the procedure?*

In Siaya they generally trained only male health providers (which includes medical doctors, nurse practitioners and male nurses). Non-medical personnel could be trained. For example, a surgeon in South Africa taught traditional circumcisors how to circumcise using a scalpel.

## 1.4 Key Areas of Concern

**Moderator: Dr. Jim Shelton, Medical Director, USAID Office of Population and RH**

**Presenter: Dr. Douglas Huber, Management Sciences for Health**

**Topic: Safety and quality of care for male circumcision**

In many respects, the safety and quality of MC surgical procedures can be informed by the historical experience of male and female surgical sterilization. There is a wide range of MC settings that must be considered, from the “gold standard” approaches used for example in the Kisumu RCT, to those employed at Chogoria Hospital and at the Siaya pilot MC introduction program. Counseling on informed choice, disinhibition, and screening for medical issues are also important.

Pre- and post-operative instructions warrant special time and attention. As we learned from the Siaya pilot project, conducted in a public-sector clinical setting with male nurses (some of whom had already done a large number of procedures), MC can still lead to problems. For example, one man returned home directly following MC without adequate instruction. He rode his bike home late in the afternoon after MC because he needed to care for his parents. Due to substantial loss of blood, he could not stand up the next day and had to be brought to the health center in hemorrhagic shock. This “near miss” is a vivid example of why postoperative care and instructions are so important. Clearly written and verbal guidance is important to ensure that a patient goes home well prepared. Nurses need to communicate well and provide thorough instructions.

Asepsis must be improved. Providers did not have effective topical antiseptics to prepare the skin for surgery in Siaya. An inexpensive and simple intervention can make a significant difference. Local anesthesia for clinical procedures is also very important and fairly low risk.

Based on experience with voluntary surgical sterilization (VSS) for men and women, accurate information for complication rates may only be available from prospective studies. For some 1.25 million procedures in 50 countries over a period of eight years, underreporting of surgical complications for male and female VSS appeared to be in the range of 90 to 99 percent. There are strong institutional incentives to not report complications. Expecting a 3 percent complication rate with “minilap” procedures, complication rates of only 0.2 and 0.3 percent were routinely found. It was not uncommon to have projects reporting 10,000 sterilization procedures with no complications. Paradoxically, the few places that reported complications were not in fact the ones with problems. Rather, they actually reported complications and, as a result, provided higher quality care. Routine reporting is not where the problems are found. Typically it is in protected, confidential interviews where the most valuable information comes from.

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A suggested arbitrary range for expected complication rates for clinical MC might be between 2 and 3 percent, even up to 5 percent. Bleeding and complications are going to happen. There is no such thing as risk-free surgery.

Contextual issues are important. Unlike male and female VSS, MC is often part of a rite of passage. Male circumcision is a part of cultural rites that have been around for a long time in many parts of Africa. When talking about safety, standards of care should reflect endogenous cultural practices instead of exogenous ideas of what is acceptable. Although traditional MC may involve training for responsible manhood, certainly it is reckless to promote promiscuous sex following MC, as has sometimes been the case. Therefore, a lot more needs to be learned about sexuality and other aspects of orientation into manhood within the traditional approach to MC. There are as many different practices as there are different cultural settings. The cultural contexts may be as important as the medical protocols.

*We need to learn a lot more about sexuality and other aspects of orientation into manhood within the traditional approach to MC. There are as many different practices as there are different cultural settings. The cultural contexts may be as important as the medical protocols.*

Informed choice information needs to be widely disseminated now. We should not only worry about disinhibition in the future, because it is already a problem. Many men are circumcised each year and hence MC-associated disinhibition is already an issue.

Male circumcision should be available in public health settings to meet existing demand. Many medical personnel, including nurse practitioners and male nurses, are eager to learn and do more about MC but do not have adequate training or supplies. A lot can be done simply to improve the services that are currently being provided. The private sector can and will provide MC services, as private practitioners in South Africa and male nurses in Kenya are already doing. There is a need to work with them on cost issues, quality of care, training, and their own professional satisfaction in conducting better and safer procedures. (This is clearly important for male nurses in Kenya.) Prospective follow-up studies are needed to get a better sense of complication rates and how to reduce them. Finally, it is worthwhile to combine clinical MC services with an orientation toward healthy manhood, as in the Chogoria Hospital program. It is not just the foreskin; this is a rite of passage with wide ramifications.

**Presenter: Dr. Ina Roy, bioethics consultant and former faculty member of the University of Pennsylvania Center for Bioethics**

**Topic: Bioethical and informed consent issues**

Pertinent principles and practices that need to be put into place for ethically sound MC policies include autonomy and self-determination for people who would be subjects for or involved in an MC project. This is accomplished through the process of informed choice, which involves more than informed consent. Second, there must be safeguards for bodily integrity; the subjects themselves should be the determinants of any choices involving irrevocable change to their bodies. Finally, care is needed to ensure cultural self-determination – cultural changes cannot be imposed on societies but must be adapted by them.

#### Principles and Practices for Ethically Sound MC Policies

- Autonomy and self-determination
- Safeguards for bodily integrity
- Cultural self-determination

**Target population:** When applying the above principles to MC policy, we must choose an appropriate population for the intervention, particularly adults versus children. We cannot assume that our ideas of what constitutes an “adult” will work in all cultures.

There are clear advantages to providing MC interventions for adults. It is far easier for adults to understand information than for neonates. Adults have experience with comparing risks and benefits and have more fully formed ideas about how these are particularly important to them. For example, some adults may prefer MC because of perceived long-term benefits, while others may feel it's not worth the risk or discomfort. Also, adults are the current population of interest; in the case of MC and HIV, adults are sexually active whereas neonates will not be for many years to come.

There is also ample rationale for considering MC interventions for children. Male circumcision is generally less complex with children, involving, for example, less bleeding. Also, some prospective studies have suggested that prepubescent MC may be particularly associated with reduced HIV risk. Finally, in some cultures, practitioners of circumcision may already have child-appropriate experience, skills, and equipment.

*Some say that MC interventions should not be considered for children because they cannot give their consent. But we often give parents the right to consent to physical changes if they are in the best interest of the child (childhood vaccinations, for example).*

Some say that MC interventions should not be used for children because they cannot give their consent. But we often give parents the right to consent to physical changes if they are in the best interest of the child (childhood vaccinations, for example). Male circumcision can also be seen as a preventative procedure against urinary tract infections, and potential future renal damage, in children.

***Informed consent:*** Informed consent is more than a lengthy form and signature. It must involve an informed choice. To be informed, a person must be educated about the procedure and aware of opportunities for follow-up care. To provide consent, a person must assent to exactly and only that procedure and to the costs of the procedure.

The onus to ensure valid consent for an individual is especially important in three instances – if the procedure 1) is irreversible; 2) includes a process that may involve emotional or physical pain; and/or 3) may result in permanent damage including functional deficit. Male circumcision fits all three of these possibilities. Therefore it is vital that adolescents (not just their parents) as well as adults be fully involved in informed choice.

The informed consent process involves describing the procedure and the risks and benefits to self and others. Alternative procedures and options available to the client should be presented. This needs to be done at a level and in the type of language appropriate to the individual and culture, including use of translators. Potential participants should be able to ask questions in a culturally appropriate environment. For example, people in some cultures prefer a group question-and-answer session rather than an intimidating one-on-one session with the health care provider. Some believe that a waiting period helps people give consent. While a 48-hour period may permit a person time to reflect, it can be onerous to poor persons traveling by foot for many hours to seek MC services. An alternative to a waiting period is to begin giving people full information about the procedure before they decide to seek health care services.

***Cultural self-determination:*** There is some concern about distinguishing “cultural hegemony” from cultural adaptation. Persons within the culture must be the ones making the decision about whether to incorporate new practices into their community. Researchers and external policy makers should assist in this process by articulating both risks and benefits as well as suggesting ways of implementing research and policies. The onus is on the MC programs to verify there are overall benefits to the specific local culture. Coercion – in the form of making it practically difficult for persons to refuse to accept a policy or procedure – must be avoided in any form.

Finally, it must be acknowledged that there are many differences between FGC and MC. Arguments that one is not ethical do not mean that the other is not ethical.

**Presenter: Dr. Ward Cates, President, Family Health International**

**Topic: Behavioral implications, including the possibility of a “disinhibition effect” associated with MC for HIV prevention**

The term “disinhibition” may be defined as an increase in unsafe behaviors in response to perceptions caused by the introduction of a preventive or therapeutic intervention. It is not a new idea and applies to any field of public health, not just HIV prevention. A release of inhibited behavior, namely an increase in unsafe behavior, is in fact a by-product of almost every curative and preventive intervention we have (for example, seatbelts and reckless driving, chest x-rays and tobacco use). It has been with us for centuries and can be

*An increase in unsafe behavior is in fact a by-product of almost every curative and preventive intervention we have.*

*If there was ever a chance to work with men, MC is it. There is an ongoing opportunity to talk with men about what MC is – just one of many options among the available interventions.*

addressed prospectively. Epidemiologists can model out beforehand what the risk-ratio from disinhibition would be. The important thing is to address disinhibition in pre-intervention counseling (the informed consent process) and in post-intervention counseling and follow-up, at both the individual and population levels. We have to recognize disinhibition as a reality and address it constantly.

One of the more optimistic approaches in the RH and HIV arena is how to involve men in choices for their sexual health. If there was ever a chance to work with men, MC is it. There is an ongoing opportunity to talk with men about what MC is – just one of many options among the available interventions.

## 1.5 Breakout Sessions

*Participants broke into five smaller groups to discuss various topics related to MC and then present conclusions and recommendations back to the larger group. Three underlining themes emerged in the groups’ conclusions.*

- Male circumcision promotion and large-scale implementation should not begin without the results of the RCTs. Most of the groups’ recommendations were made with the understanding that they would not be implemented unless the RCTs prove MC to be efficacious in reducing HIV prevention. However, there was agreement that we cannot and should not have to wait for the RCT results to begin building the infrastructure for MC implementation.
- Male circumcision programs will only be successful if they are country- or region-specific and are created and implemented with knowledge of and conformity with national or local laws and cultural and religious norms.
- Standardized MC guidelines are needed for both clinical and counseling procedures to ensure high-quality MC services.

### **1.5.1 Neonatal and Child MC Issues**

Following a data overview presentation by Dr. Edgar Schoen of Kaiser Permanente Hospitals of California [23], the neonatal discussion group focused on how and when to implement MC for infants. The discussion led to the issue of whether to implement MC as part of child health services and/or as an HIV intervention program. In settings where MC is not practiced, promotion of MC as part of child health might be more acceptable. However, MC would more likely be adopted if it was promoted as part of an HIV intervention program. Others recommended that MC also be included in other health programs, such as those addressing prevention of mother-to-child HIV transmission (PMTCT).

Male circumcision programs need to include information dissemination and education to help those already practicing circumcision to promote safer procedures. Standard MC procedures and the means to ensure quality of care must also be developed. All MC practitioners should be retrained according to these guidelines. Nurses and midwives must be included as MC practitioners, especially in settings where infants are born at home.

Program implementation could start by improving MC standards, setting up country-specific infrastructure, and encouraging community education and dialog even before the RCT results are available.

### **1.5.2 Quality of Care, Including Training, Safety Regulations, Counseling Methodologies, etc.**

This discussion produced three main points. First, MC programs should focus on a comprehensive systems approach that incorporates the specific views and practices that already exist on MC in respective countries. Different clinical approaches are needed for different groups, cultures, and regions, and both medical as well as traditional approaches should be available. Secondly, there is a need for standardized MC procedures and techniques to address infection prevention and complications management, training and accreditation, and supplies/equipment standards. Medical and traditional practitioners should receive competency-based training on these clinical procedures.

Lastly, counseling is an important and essential component of quality care. Practitioners must be well versed in client rights and able to present an understandable and culturally appropriate consent procedure. MC programs need to abide by national laws, including parental consent laws. Practitioners also need to be able to provide their clients full information on the partial protection afforded against HIV, possible complications, and the potential for behavioral disinhibition. MC counseling could become a useful entry point for RH counseling more generally.

### **1.5.3 Potential Advantages and Concerns of Private-Sector Approaches, Including Cost Issues**

A clear advantage of performing MC in the private sector is the potential increase in accessibility and coverage. The private sector may be able to help increase the quality of MC procedures and standards. Practitioners could be well trained and would also have the mechanisms in place to monitor and improve their practice as they see fit. The private sector could also facilitate further research, helping to uncover data on acceptability and side effects of MC.

Concerns include identification of appropriate practitioners, training, and education on counseling, specifically on the social and cultural aspects related to MC. Standardized MC procedures would be a necessary tool for this training. Additional funding for these practitioners would be necessary as an incentive to provide the services. The cost of supplies and equipment would also need to be sufficiently low to increase practitioners' willingness to perform MC.

#### 1.5.4 Women's Roles and Issues, Including Relation to FGC Advocacy and Cervical Cancer

Since MC is currently seen as a cultural and religious practice, women – as important carriers of communal traditions – also need to be involved in MC awareness and implementation. Women could be the starting point of MC promotion for infants and adolescents since child-rearing responsibilities are often their purview. Any MC program must be culturally appropriate and work from within the system.

Promotion of MC could complicate the campaign to stop female genital cutting (FGC). In places where FGC is practiced, MC is nearly always also practiced. Female genital cutting must be de-linked from MC and the international community and non-practicing FGC/MC communities must be able to discuss the issues rationally, concluding that FGC is a harmful practice while MC may provide various health benefits and advantages.

*Female genital cutting must be de-linked from MC and the international community and non-practicing FGC/MC communities must be able to discuss the issues rationally, concluding that FGC is a harmful practice while MC may provide health benefits and advantages.*

Cervical cancer is one of the leading causes of death for women. Lower rates of cervical cancer have been found in areas with high rates of male circumcision. Although there may not yet be total proof of a cause-and-effect connection between MC and cervical cancer, a recent seven-site international study found a significant association between lack of MC and higher prevalence of HPV infection in men as well as lower cervical cancer rates in partners of circumcised men who had multiple partners compared to the partners of uncircumcised men with multiple partners [8]. MC should be added to the cervical cancer research agenda.

#### 1.5.5 Integration With Other RH Services

Male circumcision should be introduced into RH services within a spectrum of three scenarios of program activity. The first scenario is to work with modified traditional/medicalized MC practices along the model of Chogoria Hospital's "Seize the Day" program. The second is to respond to existing demand for MC services without actively promoting MC as an HIV prevention intervention. Activities within these first two scenarios would help build a knowledge base of clinical, counseling, and cost data that would be essential preparation for scaling-up of services if the RCTs indicate that MC definitively has a substantial protective effect against HIV. Third (should RCTs show a clear protective effect for MC), there would be a need for a far more active approach, including the possibility of vertical programs to respond to the anticipated rapid increase in demand.

*Should RCTs show a clear protective effect for MC, there would be a need for a far more active approach, including the possibility of vertical programs to respond to a rapid increase in demand.*

Some people view integration of MC with RH services as a potentially effective way to get men more involved in reproductive health in general. However, maintaining the quality of both services once they are integrated is still a challenge. There is concern that the quality of RH might be compromised since MC is a medical procedure and hence might be performed by practitioners who are less knowledgeable about RH services generally. RH services must be able to attend to their own program needs before introducing and integrating another component. However, there is a potentially important opportunity, with adolescents in particular, for further RH counseling following MC.

Lastly, the creation of MC programs should start locally. There are various cultural and religious differences that could become barriers to successful implementation. In addition, acceptability studies must be conducted in different cultural settings, especially in places where MC is not a rite of passage or is not traditionally practiced at all.

## 1.6 “Where do we go from here?”: Key Policy and Implementation Issues

**Moderator: Peter McDermott, UNICEF/USAID Africa Bureau**

**Panelists: Ronald Gray, Douglas Huber, and Dipo Otolorin**

*The panelists were charged with commenting on next steps for MC, addressing whether it is appropriate or not to promote MC now for HIV prevention and/or male RH, and describing the criteria for making such determinations.*

**Ron Gray:** While we await the results of the RCTs we need to start observational studies on traditional MC practices. We should provide training to medical and traditional practitioners and emphasize certification of training and equipment. We should also consider integrating MC with other services, such as condom promotion. However, there is a need for caution, because we need to learn much more about how to prevent disinhibition. Moreover, the observational data could be confounded, and RCTs are required to determine the efficacy of MC for HIV prevention before this procedure is actively promoted as a means of HIV control. If RCTs demonstrate a protective effect, MC could be very beneficial; in fact, MC could become one of the most powerful HIV prevention interventions we have. But this beneficial protective effect could readily be offset by any significant increase in risky behavior. Moreover, it is premature to promote MC in areas where it is not done traditionally, especially if the message is that MC is protective against HIV/AIDS because this could engender false expectations of protection and thus promote disinhibition.

**Douglas Huber:** The question of disinhibition needs to be addressed now, not in the future. There are millions of men already circumcised and undergoing MC without any intervention, and some of these men may well be getting the wrong message that MC is fully protective against HIV. There is a compelling and urgent need for disseminating accurate and balanced information on MC. This is not to promote MC as conferring complete HIV prevention but to make sure accurate information gets out in an understandable package. We need to let the local decision-makers know what the advantages and disadvantages are; it is for them to take action.

It is important to put MC within a holistic context and realize that it is an opportunity to integrate improved educational messages into the traditional MC experience; for example, to introduce “ABC” (Abstinence, Be faithful, use Condoms) concepts. We need to counter misinformation and dangerous messages that are part of some traditional MC practices in the transition from boyhood to manhood. The risks to young men now practicing traditional MC are great in terms of the way they are introduced to unhealthy sexuality and related behavioral messages. More work needs to be done in order to move forward. As part of MC-related education for young men, there is an opportunity to introduce the A, B, and C messages as well as the idea of VCT being a positive, courageous, and responsible male behavior. This is not just about improving MC surgery; this is about changing the entire educational package associated with traditional MC.

**Dipo Otolorin (JHPIEGO):** Although we must wait for the RCT results before actively promoting MC for HIV/AIDS protective purposes, we need to support existing MC programs. Male circumcision should be a component of the ABCs of prevention. We are not going to stop traditional MC. We need to work with communities that support MC, as Judith Brown discussed in her presentation. This is especially true since, unlike FGC, we have no evidence to show that we should stop MC services. While waiting for the RCT results, let us focus on improving the quality of care, safety, training, and standardization of techniques. We should identify who the providers are and help them perform MC safely and without complications. Action must be taken now and not postponed until the outcomes from RCTs are known. We should support existing MC programs and the cultures that support it. Let's prepare to scale up now, even as we are awaiting the RCT results.

**Participant Discussion:** David Stanton (USAID Office of AIDS) noted that we need more discussion of pilot projects, operations research (OR), and operational issues such as what levels of training and quality assurance are necessary in various settings in order to be ready to hit the ground sooner if RCTs show a protective result. We need interventions that help identify better practices; we need prospective OR studies and/or modified clinical trials to get accurate complication data. Service delivery programs will not provide this information. At this point in history we have a tremendous opportunity to get ready in anticipation of the RCT results. A scientific breakthrough requires a relatively slow process of operationalization, such as with MTCT. The three- to five-year duration of clinical trials may seem long, but so will the process to develop consensus, national standards, and community buy-in on MC. We have to start now and, with this in mind, USAID plans to support one or two pilot sites in providing MC not as an HIV prevention intervention but as part of male RH services. This will be coupled with rigorous operations research to answer the questions raised today and other questions we haven't yet thought of. We want to get closer to or even ahead of the curve on this issue.

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Male circumcision is a local decision and we have a responsibility to make sure we get the information out to our local communities so they can discuss it. One meeting participant admonished that MC affects women as well and we need to include them. The Siaya study pointed out that women (mothers, wives, and partners) are strong proponents of MC – 88 percent of mothers wanted their sons to be circumcised. Male circumcision choices need to be integrated with RH issues for both women and men. There was a call for assessing the relative cost of MC introduction versus other types of interventions.

A physician from South Africa raised the concern that despite the presentations made on MC acceptability studies, he had yet to see any interest expressed in MC in his medical practice in an area where MC is not traditionally practiced. He cautioned that there may be a Western cultural bias at work here, akin to “cultural hegemony,” that might inflate estimates of demand for MC services. There is a need for equity and balance to ensure that we do not improve MC services for some but then not offer MC to others.

## 1.7 Summary and Conclusions

### Recap of the Day: Peter McDermott, UNICEF/USAID Africa Bureau

While it may be premature to actively promote MC, we should nevertheless take a number of critical actions now. There is much to do, but explicit promotion or demand creation is not advisable at this time in the absence of definitive evidence. There is also the unresolved issue of whether we should move to support neonatal MC while at the same time looking toward youth and adult MC. We need to start building the foundations for successful MC implementation if and when favorable results derive from the RCTs.

#### Main Topics for MC as a Potential HIV/AIDS Prevention Measure

1. Locality and context
2. Policies, regulations and guidelines
3. MC information dissemination
4. Clinical management protocols and guidelines
5. Program design
6. Cost and resources
7. Ethical concerns

There were seven main topics from the day's discussions, which may serve as a roadmap for those interested in MC as a potentially important public health component of HIV prevention programs:

**1. Locality and context:** We need to learn much more about the communities where MC programs may be put into place. As we heard from representatives from places such as South Africa and Cameroon where MC is traditionally performed, we do not need to await the results of RCTs in order to learn about applicability, acceptability, and feasibility in local environments. Local context assessments from an anthropologic, ethnographic, and cultural perspective informed by a gender dimension can commence now. We need to start working on acceptability and feasibility studies to identify and overcome barriers if and when MC is ready to be fully implemented. We need to learn about existing practices, identify community leaders, and investigate what will work and what won't in specific regions and communities.

**2. Policies, regulations, and guidelines:** We need to understand the policy and legal dimensions better. It is not clear that there is a policy framework at the national level that will cover MC interventions. There is some knowledge of medical and traditional practices, but we need to review country policies and regulations regarding medical practices, safety, age, etc., that can have implications for MC implementation. We need to undertake an assessment and analysis of potential constraints at the national level in order to develop successful programs.

**3. MC information dissemination:** We need to get current knowledge on MC into the public domain in a careful, planned, and deliberate manner without sending mixed messages. We need a public and professional dialogue at national and regional levels in order to build a local constituency and favorable environment for MC. We need to craft messages and strengthen professional and community alliances to build a broader constituency.

**4. Clinical management protocols/guidelines:** Clinical management requires protocols and/or guidelines on quality, training, certification, safety, etc. Other issues such as referrals, emergency management, consumables, age considerations, also need to be considered and prepared for. Other guidelines will be necessary to address integration with existing services (antenatal care, PMTCT, etc.) as well as for public- and private-sector services provision.

**5. Program design:** Program design and careful strategy formulation are needed if we wish to make existing practices safer and create culturally acceptable pilot interventions. Program design must antici-

pate possible national “roll out” of MC. Key operations research agenda questions must be identified, including the relationship of MC to microbicides, HSV-2 transmission, and other determinant factors.

**6. Cost and resources:** There are potentially huge cost implications of public service scale-up for MC, even with expected economies of scale. There are also concerns related to equity in access. Costs and resources need to be anticipated to ensure equity in terms of access and quality of MC. We need to look at the national estimated costs of MC and look creatively at how we can reduce or allocate other funds.

**7. Ethical concerns:** Finally, we need to examine the ethical considerations of MC services as they relate to bodily integrity and informed choice and consent, especially for neonates and children.

## 1.8 Final Discussion and Closure of Formal Meeting

### Concluding Remarks by Duff Gillespie and Kevin O’Reilly

*When you compare the knowledge base for what we are doing now (at great cost) with the MC knowledge base, our knowledge about MC is actually pretty robust.*

**Duff Gillespie, USAID Deputy Assistant Administrator for Global Health:** Let’s reflect on what we currently have available to address HIV/AIDS. Male circumcision may be invasive but it also happens to be the most common surgical procedure in the world. Unlike MTCT programs, it is already widely practiced. The frustrating reality of the HIV challenge is that in the early stages we implemented things that did not work and implemented other things that have worked for reasons we do not fully understand. When you compare the knowledge base for what we are doing now (at great cost) with the MC knowledge base, our knowledge about MC is actually pretty robust. The MC horse is out of the stable. Private providers are responding to demand and will attempt to earn money from performing it. We should consider the fact that there are probably more men who are circumcised than are using condoms. We need to avoid being a bit ivory-towerish. We cannot wait two to three years to move forward. When compared to MC, we are actually implementing some programs based more on hunches and good intentions than on sound scientific evidence. The discussion has been rich. We cannot make perfect decisions, but this type of meeting can help us to make the best decisions we can, armed with the best information at hand.

**Kevin O’Reilly, WHO, Geneva:** As outlined in an editorial by Ward Cates and others some 15 years ago, there is no magic bullet for HIV/AIDS. We all have a strong desire to find one and it does not exist; MC is not a magic bullet either. At the very successful “ABC” meeting yesterday, it was concluded that multiple prevention approaches are needed: all of A, B, and C... and perhaps a D will emerge. We need to think about MC in the A and B and C context.

*There is no magic bullet for HIV/AIDS. We all have a strong desire to find one and it does not exist; MC is not a magic bullet either.*

We must keep in mind that we do not have MC intervention data yet. In the meantime, while we are waiting we should focus on the following issues. First, we need to address disinhibition. We need to address a fatigue that may have set in. Rather than lament a lack of progress, we should point to how much worse the epidemic would have been without the various interventions that are already in place, and redouble our efforts with a robust armamentarium of approaches. We need to implement other prevention methods where MC is insufficient, such as those places where MC is practiced but HIV prevalence is relatively high anyway. With MC, we still need to proceed with caution and continue the prevention efforts we’ve practiced in the last 20 years. HIV/AIDS requires a multifaceted, multilayered response. MC is just one of the components that need to be considered.



## 2.0 Day 2 - Smaller Working Group Meeting (held at PATH-DC Offices)

The day-long meeting on Sept. 19 was attended by 29 experts in RH, MC services, epidemiology, and related disciplines, who explored next steps for MC activities, including research, training, and introduction of pilot clinical services (see attached participant list and agenda). The discussions focused on the question, “How do we best go about, in real life situations, providing voluntary, affordable, safe MC services in developing countries?” The meeting’s four specific objectives were to draft rapid assessment tools; draft a “generic” MC introduction strategy; prioritize a list of research gaps; and prioritize a list of training needs.

### 2.1 Informal Panel: “How best to move MC programs forward, and with which populations?”

**Judith and Richard Brown:** There are four key populations in which to consider MC programs: 1) where infant circumcision is widely practiced; 2) where pubertal and/or adult MC is traditionally practiced; 3) where MC is not traditionally practiced yet demand is building; and 4) where the results from RCTs will become available. Interventions will not be necessary in all settings. For example, although training and improved service are important, an over-professionalizing of MC might actually reduce the number of safe circumcisions performed. Small practical steps can be taken now, through, for example, an exchange of personnel between Kenya and Zambia for three months of peer-to-peer training. We should not give priority to improving MC techniques in countries where it is already practiced. Our primary objective is to reduce the spread of HIV/AIDS, and just improving MC technique is not going to have a direct impact on HIV incidence.

**Robert Bailey:** One barrier to the introduction of MC is the fear in ministries of health that people will go to traditional practitioners where complications rates are perceived to be high. While some frequency data exist for MC complications, there is no denominator to calculate a rate. Hence we need to conduct prospective studies of MC in both traditional and clinical settings to provide empirical data on complications. Standard MC policy in the United States and Canada is to provide parents with the best information on risks and benefits for informed choice, but this information is not available in developing-country settings. It is important to educate providers at all levels about the potential risks and benefits of MC.

**Douglas Huber:** We need to keep the larger context in mind and address the disinhibition message. Given that many men are already being circumcised, disinhibition is a major priority for all men now, not just future clients of MC programs. The larger context must be kept in mind that MC is not a magic bullet to reduce HIV/AIDS and we must also promote healthy sexual behaviors within existing MC practices.

The group discussed how to improve existing MC practices in places where complication rates are thought to be high, such as the Eastern Cape region of South Africa. Transferring of expert MC techniques should be a high priority in order to sustain MC acceptability. It is important to improve the techniques where traditional MC is performed and to utilize traditional providers as an entry point for HIV prevention and RH messages. In many places, MC is an important rite of passage and boys are very receptive to learning. The teaching that occurs during this period involves lifelong learning, and this learning will probably

have more of an impact on African men than at any other time in their lives. Donors face the dilemma of limited resources and the need to concentrate them where they will have the greatest impact on prevention. This meeting should keep the focus on MC for HIV prevention, not MC for its own sake.

## 2.2 Components for a Draft MC Introduction Strategy

*Participants divided into three groups:*

*Group 1. Assessment strategies and tools*

*Group 2. Components for clinical protocols*

*Group 3. Informed consent and counseling*

### **Group 1. Assessment strategies and tools:**

The group made recommendations in two areas – rapid assessment strategies and complication studies.

**Rapid Assessment:** There is a need for rapid assessments as well as for “buy-in” from national, provincial, and local political and traditional authorities with active participation of key institutions (MOH, health facilities, etc.). Data need to be collected from multiple sources at different levels, including focus groups with young men and women, adults and elders, MC providers, and commercial sex workers. Quantitative survey data are also needed from representative samples of these groups. Data need to be collected on current MC practices, including clinical procedures, availability, institutional cost appraisals in various settings, and logistical issues (training needs, inventory of instruments, supplies and consumables, etc., both in clinical and traditional settings). Counseling issues need to be addressed in data collection. There is already a range of validated instruments available that can be adapted for rapid assessment (e.g., those developed by Bailey et al. in Kenya, both in Kisumu and Siaya, as well as for the RCTs in Uganda and South Africa). In addition, the London School of Hygiene and Tropical Medicine has conducted an acceptability study of MC in the Kwa-Zulu/Natal region of South Africa.

MC-related questions should be added to ongoing or planned Demographic and Health Surveys (DHS) and Behavioral Surveillance Surveys (BSS). A recent large BSS in Ethiopia asked about MC (77 percent of men nationally reported being circumcised, including 49 percent in one district with particularly high HIV prevalence). The 2003 DHS surveys in Kenya, Uganda, and Mozambique, and perhaps other countries, will ask about MC status. The Zambian Sexual Behavior Survey will include several questions about whether men are circumcised or not, their potential interest in being circumcised if they are not already, and perceptions of a possible relationship between MC and hygiene/health. Other potential survey questions could focus on resumption of sexual activity after surgery, sexual pleasure, and gender-related issues associated with MC.

**Complication Studies:** Prospective studies to assess complication rates are needed for traditional and clinical MC for adults, adolescents, and infants. Priority should be given to the countries where RCTs are underway (Uganda, Kenya, South Africa). Ideally, variations in complication rates should be assessed at several different sites in South Africa. There is a need for more information on neonatal and child circumcision in regions such as West Africa. A site outside of Africa, (e.g., Haiti) could also be included. An updated literature review is required to ensure that there are not any new complication studies from Africa (to date, evidently only three have been conducted).

Key methodological issues relate to sample design, sample size, timing of data collection in relation to the MC procedure, and a potential bias toward the higher quality MC services (i.e., the Kenya and Uganda RCTs). It would be useful to employ a retrospective study design.

A multisite study of complication rates in traditional and clinical settings for neonates, adolescents and adults is highly recommended.

### ***Group 2. Components for clinical protocols:***

Various clinical and technical requirements for adolescent and adult MC were identified. The group recommended the improvement of counseling for informed consent/choice; assessment of client needs; assessment of facilities; pre-operative care; surgical procedures; discussion of different procedures/techniques; post-operative care; supplies and equipment; infection prevention (for example, use of sterile instruments, “one clamp, one boy,” protection for both providers and clients); patient education (pre- and post-operative); and pain management.

Training considerations included developing methods to assess current competencies and cultural practices and then providing additional group and one-on-one training as needed. A performance checklist to assess competency was also suggested. Important core techniques for practitioners to learn include infection prevention, education and counseling, complication and pain management, and optimal MC techniques. There is also a need for tools to support training and clinic systems such as anatomic models, job aids, monitoring, and supervision. A training curriculum could be developed with modules available on-line. An MC Technical Working Group should be set up to help assess the relative merits of MC surgical techniques and related medical devices (Terra-clamp, PlastiBell for adults, etc.), as well as to work toward formulating international standards and addressing regulatory issues such as FDA approval. In addressing supplies and equipment, quality and price will influence the capacity for resupply.

Male circumcision and HIV prevalence rates as well as the local cultural context will influence training. For example, there may be potential friction between the medical establishment and traditional practitioners. Low MC prevalence areas might bring in provider trainees from high MC prevalence areas where the caseload (and presumably technical expertise) is higher.

### ***Group 3. Informed consent and counseling:***

Signed informed consent forms may, at times, be culturally unacceptable, and “information overload” should be avoided. Key components should include benefits and risks, potential for risk reduction, the patient’s responsibility for self-care, the need to involve a family member or friend (i.e., a “buddy system” to ensure post-operative safety), and the vital need to take advantage of the post-op recuperation period to introduce strong educational messages about sexual responsibility, gender roles, and socialization – i.e., the “ABCs.”

Easily understandable information, education, and communication (IEC) materials that clients can refer to later will help them retain needed information. IEC materials should be age- and culturally appropriate as well as geared towards different groups, such as adolescents, adult men and their spouses, and the parents of infants. In addition to responsible sexuality and “ABC” types of messages, IEC materials should challenge erroneous community beliefs; present the potential advantages/benefits as well as risks/disadvantages, complications, and pre- and post-operative care needs; and stress the need for prompt treatment of STDs.

Counseling needs will inevitably differ between adolescents, adult men and their spouses, and the parents of children and infants. In areas such as Cameroon, where neonatal MC is already a cultural norm, parents may not know of any medical advantages and risks. Counseling should describe the procedure, post-operative care, and potential complications. It may also address and compare clinical versus traditional practices. Counseling must address local cultural preferences for how the foreskin should be disposed (for both neonatal and adolescent procedures); i.e., should it be buried with appropriate rituals or ritually eaten, or may it be used for research purposes or even skin grafts for burn victims, etc.?

The type of approach employed by Chogoria Hospital's "Seize the Day" program should be considered for the post-operative recuperation period (approximately one month). This is a time to address gender/violence against women issues, condom use, and the potential for behavioral disinhibition. In areas where FGC is practiced, MC should be clearly de-linked from FGC, and should not be viewed as promoting or reinforcing FGC norms.

## 2.3 Key Follow-Up Priorities

In the afternoon, two groups were formed to discuss 1) possible locations, challenges, and planning needs for introducing MC into high HIV prevalence areas where MC is not commonly practiced, such as Zambia, and 2) how to work within traditional settings where MC is routinely practiced, such as in most of Kenya and the Eastern Cape region of South Africa.

### ***Group 1. Introducing MC services into traditionally non-circumcising, high HIV prevalence areas (Zambia, Haiti):***

In view of USAID's planned support for pilot studies of MC as part of male RH services (not as a mainly HIV intervention), the group focused on Zambia, where USAID/Lusaka and the Zambia MOH have expressed interest in pursuing acceptability and feasibility research for pilot MC services. There is evidence of demand for clinical MC in Zambia, but lack of adequate practitioners and resources is reported in Lusaka and elsewhere. The group recommended convening a stakeholders meeting within the next couple of months to present accurate and balanced information on the risks and potential benefits of MC and to explore the possibility of some pilot provision of safe and affordable MC services, ideally integrated with male RH programs. MC-related questions will be added to the next Measure II Sexual Behavior Survey (in spring 2003), and PSI/AIDSMARK may conduct some additional focus group discussions and interviews with key informants. JHPIEGO will assist with MC clinical training needs, and the USAID-funded Horizons program could possibly support an OR study in Zambia.

Suggested next steps include:

- a) Hold a stakeholders meeting with doctors, nurses, other potential providers, and the requisite regulatory bodies
- b) Develop national standards and guidelines
- c) Develop a learning resource package modeled on JHPIEGO training materials
- d) Identify in-country "champions"
- e) Conduct a training needs assessment
- f) Establish a context for MC within model male-friendly RH services/clinics
- g) Link with VCT and STD screening
- h) Work with faith-based organizations such as the Adventist Hospitals, which reportedly are providing some clinical MC services

Haiti may also be interested in holding a similar stakeholders meeting to assess the interest and potential demand for adult or neonatal MC. (A future stakeholders meeting might also take place in the neighboring Dominican Republic.) The USAID Haiti Mission and its local partners may be particularly interested in considering integrating neonatal MC into PMTCT services.

***Group 2. Working with traditional providers of adolescent MC services in sub-Saharan Africa:***

The group discussion reflected both the Chogoria Hospital experience in Kenya (described on Day 1 by Judith Brown) and recent work in the Eastern Cape of South Africa, under the leadership of Dr. Mamisa Chabula. Dr. Chabula's efforts over the past two years have resulted in new government regulations covering traditional MC providers. Some 50 MC practitioners and 100 care provider-educators have been trained to provide services for thousands of youths each year, using a curriculum developed in collaboration with the University of Port Elizabeth.

The group recommended that a rapid assessment be conducted of the Eastern Cape program, as well as the one at Chogoria Hospital. A concept paper for funding will be drafted by Dr. Chabula and her colleagues. It will recommend assessing what MC services are already available in South Africa, what is working and what is not, and potential recommendations for improvement. Assessment of the Eastern Cape program should address training, curriculum and teaching methods, and how to improve traditional MC services generally. The project should include South-to-South sharing of lessons learned between sites, such as the Chogoria Hospital in Kenya and the Eastern Cape.

It may also be feasible to re-introduce MC services into the currently non-circumcising region of Kwa-Zulu/Natal, which has very high HIV prevalence (as high as 40 percent). Male circumcision was traditionally practiced here until the time of King Chaka Zulu in the early 1800s, but has since been abandoned. The London School of Hygiene and Tropical Medicine is collaborating with a research center in Kwa-Zulu/Natal that might provide good infrastructure for both an intervention and for monitoring (i.e., an ongoing demographic survey every three months across a representative sample of households). A survey of 100 men in the area revealed that 56 percent would be willing to undergo MC if it were performed safely and at low cost.

The group recommended that WHO host a technical consultation on MC in traditional and informal medical sectors. Such a meeting would help develop a consensus on standards of practice, medical and educational issues for MC with regard to HIV prevention, adolescent RH, etc. The consultation could take place before the results of the RCT are known, not to create policy in advance of the evidence, but to discuss traditional practices, standards, rites of passage, etc. This type of consultation would be consistent with previous WHO work on, for example, the use of antibiotics and syndromic approaches within the informal sector. External donor support would probably be needed to pay for this consultation.

A suggestion was made, especially in settings where MC is not traditionally practiced, to establish "post-MC clubs" for young men to be able to come back after the procedure, talk about their new MC status, discuss the "ABCs" of prevention, get condoms, etc. This might help compensate for the absence of the group education and socialization experience that occurs during the seclusion period of traditional initiation/rites of passage practices.

### 3.0 Final Recommendations from the Day 2 Meeting:

- Facilitate rapid assessment of MC through sharing of existing protocols and data collection instruments.
- Carry out a prospective, multisite study of complication rates for MC (both traditional and clinical) among adults and neonates. Priority should be given to the three countries with RCTs (Kenya, South Africa, Uganda).
- Convene a MC Technical Working Group meeting to review and compare surgical and other medical procedures, medical devices, and guidelines for adolescent/adult and possibly neonatal MC. JHPIEGO would host, and Dr. Dipo Otolorin would chair, the meeting.
- Conduct a cost-effectiveness study to assess the cost of scaling-up and sustainability, perhaps based in part on the experience of the Siaya, Kenya, MC introduction project.
- Work with the media, i.e., be more proactive in providing balanced and accurate information to the press and possibly in responding to internet websites that may spread misinformation (such as materials posted by the more extremist anti-MC groups).
- Implement MC assessment and introduction studies in Zambia, Haiti, and possibly Kwa-Zulu/Natal, South Africa. Along the lines of the three clinical trials in Kenya, Uganda, and South Africa, there should be multiple sites for introducing MC as a voluntary aspect of male RH services. The sites should communicate with one another to ensure some degree of comparability. Cameroon was also mentioned as a possible site.
- Possibly assess different types of MC practices regarding their relative efficacy against HIV. Some forms of MC may only have a partial effect if the receptor cells are not removed to the same degree. A multisite study of complications could also look at different practices and styles of MC, but needs to be carried out as a non-intervention so as not to influence the practices under study.
- Encourage WHO to co-host with JHPIEGO a technical consultation on MC in traditional and informal medical sectors. The meeting would help develop a consensus on standards of practice, medical and educational issues with regard to HIV prevention, adolescent RH, etc. Such a consultation could take place before the results of the RCTs are known, not to form policies in advance of the evidence, but to discuss traditional MC practices, standards of care, integration of RH/HIV prevention into traditional rites of passage, etc.
- Disseminate the results of this meeting, via a three-page brief, to key government officials and other stakeholders.

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### *Cover Page Graphic:*

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# Appendix 1

## Participation List for September 18, 2002 (\* Participants for September 19 meeting)

### **Male Circumcision: Current Epidemiological and Field Evidence – Program and Policy Implications for HIV Prevention and Reproductive Health**

Sponsored by USAID Office of HIV/AIDS, AIDSMARK (PSI, PATH, MSH), JHPIEGO

Date: Wednesday, September 18, 2002, 8:30 – 4:30

Venue: Council on Foundations Conference Center (1828 L St. NW, Washington, DC)

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#### Participant List

Saifuddin Ahmed, Johns Hopkins University	Shanti Conly, USAID
Wendy Albright, USAID	Katherine Crawford, USAID
Rose Amolo, CEDPA	Kelly Curran, JHPIEGO *
Bertran Auvert, University of Paris, France *	Holly Fluty Dempsey, USAID
Robert Bailey, University of Illinois at Chicago *	Carl Dieffenbach, NIH/NIAID/DAIDS
John Berman, AIDSMARK	Regine Douthard, USAID
Jane Bertrand, JHU/CCP	Nicholas Eberstadt, American Enterprise Institute
Judith Brown, Nazareth Hospital, Kenya *	Erin Echert, JSI
Richard Brown, Nazareth Hospital, Kenya *	Abdelhadi Eltahir, USAID
Jean Robert Brutus, Family Health International -Haiti *	Paul Embree, University of California, Davis *
Frederick Burkle, Jr., USAID	Brynn Epstein, US Census Bureau
Martha Butler de Lister, Fundacion Genesis, Dominican Republic	Donna Espeut, ORC Macro
Aly Cameron, JHPIEGO *	Mary Lyn Field-Nguer, FHI
Connie Carrino, USAID	Nomi Fuchs, USAID
Michale Carael, UNAIDS	Mark Gersovitz, Johns Hopkins University
Chris Castle, Population Council/Internat. HIV/AIDS Alliance	Alan Getson, USAID
Willard Cates, Jr., FHI	Duff Gillespie, USAID
Mamisa Chabula, Cacadu District Municipality, South Africa *	Ronald Gray, Johns Hopkins University
Nada Chaya, PAI	Edward Green, Harvard University
Laryssa Chomiak, USAID	Celeste Gregory, USAID
Sam Clark, PATH *	James Griffin, USAID
Lee Claypool, USAID	Daniel Halperin, USAID *
Anne Clayton, USAID	Janet Hayman, USAID

# Appendix 1

## Participation List for September 18, 2002

(\* Participants for September 19 meeting)

James Heiby, USAID

Rebecca Henry, MACRO International

Stephen Hodgins, USAID/Zambia \*

Malea Hoepf, Population Council Horizons Program

Rod Hoff, NIH/NIAID/DAIDS

Petra Marian ten Hoope Bender, Int. Conf. of Midwives, \*  
Netherlands

Ruth Hope, The Synergy Project

Amanda Huber, USAID

Douglas Huber, MSH \*

Silvia Bomfim Hyppolito, Federal University of Ceará-Brasil, \*  
Brazil

Roy Jacobstein, Engenderhealth \*

Rachel Jean-Baptiste, University Research Co.

Jerry Jennings, USAID

Sandra Jordan, USAID

Daniel Kabira, USAID

Montasser Kamal, Canadian International Development Agency \*

Mihira Karra, USAID

Laura Kayser, FHI

Robert Kelly, PSI/AIDSMARK \*

Tabitha Keener, USAID

Upama Khatri, USAID

Moira Killoran, Pacific Institute for Research

Susan Krenn, John Hopkins University/CCP

Robert Leke, University of Yaoundé, Cameroon \*

Khunying Kobchitt Limpaphayom, Chulalongkorn University, \*  
Thailand

Kim Longfield, AIDSMARK/PSI

Ron Magarick, JHPIEGO \*

Hally Mahler, FHI

Shawn Malarcher, USAID

Leslie Mancuso, JHPIEGO

Nithya Mani, USAID

Judy Manning, USAID

Ray Martin, Christian Connections for International Health

Nancy McCharen, USAID

Eugene McCray, CDC

Peter McDermott, USAID

Paolo Miotti, NIH/NIAID/DAIDS

Kim Mulji, Naz Foundation International, UK

Colleen Murphy, Global Health Council

Jeff Marck, Health Transition Centre

Elaine Murphy, George Washington University

Aleathea Musah, USAID

Svetlana Negroustoueva, ORC Macro

Susan Newcomer, National Institute of Health

Phillip Nieburg, CDC/USAID

Al Nimocks, Youthnet FHI

Julitta Onabanjo, UNFPA

Thomas Onyango, Ministry of Health, Kenya \*

Kevin O'Reilly, WHO \*

Emmanuel Olorin, JHPIEGO \*

Michel Pacqué, ORC Macro

Lydia Palaypay, Far Eastern University, Philippines \*

Fiona Pamplin, PSI

Gregory Pappas, ORC Macro

Bruce Patterson, Children's Memorial Hospital, Chicago

Lynn Paxton, CDC

# Appendix 1

## Participation List for September 18, 2002

(\* Participants for September 19 meeting)

Anne Peterson, USAID

Billy Pick, USAID

Glenn Post, USAID

Clydette Powell, USAID

Agma Prins, Advance Africa \*

Nina Pruyn, Advance Africa

Dimitri Prybylski, PSI/AIDSMARK

Renee Ridzon, Gates Foundation

Karrin Ringheim, PATH \*

Joana Rosario, NIH/NIAID/DAIDS

Ina Roy, Plan-A, Inc, NIMH

Monica Ruiz, NIH/NIAID/DAIDS

Naomi Rutenberg, Horizons Program, Population Council

Anton Schneider, Academy for Educational Development

Edgar Schoen, Kaiser Permanente Medical Center

James Shelton, USAID \*

RJ Simonds, CDC

Richard Skolnik, George Washington University

Freya Lund Sonenstein, The Urban Institute

Jeff Spieler, USAID \*

Elizabeth St. Clair, USAID

Judith Timyan, USAID, Haiti

Ed Tramont, NIH/NIAID/DAIDS

Johannes van Dam, Population Council

Lut Van Damme, CONRAD

Eric Van Praag, FHI

Joshua Volle, FHI

Jimmy Volmink, Global Health Council

Peter Way, U.S. Census Bureau

Helen Weiss, London School of Hygiene & Tropical Medicine \*

Carolyn Williams, NIH/NIAID/DAIDS

David Wilson, University of Zimbabwe

Sara Woldehanna, Global Health Council \*





U.S. Agency for International Development  
1300 Pennsylvania Avenue, NW  
Washington, DC 20523  
[www.usaid.gov](http://www.usaid.gov)